# The Dangerous Decline in the Department of Defense's Vaccine Program for Infectious Diseases

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For over 230 years, vaccines advanced by the US military research and development (R&D) community have dramatically reduced the impact of naturally acquired infections, not only in America's armed forces but also in society at large. In recent years, however, the military's vaccine program for infectious diseases has lost considerable emphasis, funding, and mission capability. In the 1990s, with the burgeoning concern for weaponized bioagents in Iraq and North Korea, Congress turned its attention to combating biological threats of deliberate rather than natural origin. The Department of Defense (DOD) responded by partitioning its biodefense and infectious-disease vaccine acquisition programs, with biodefense vaccines holding a higher acquisition priority and receiving more robust funding than infectious-disease vaccines. This choice has significantly eroded the DOD's ability to ensure the acquisition and availability of the right vaccines at the right time to optimally protect US forces from established and emerging natural infections now and in the future.[1]

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The DOD needs to take swift actions to revitalize its infectious-disease vaccine program and enhance the synergy between biodefense and infectious-disease activities to resolve shortfalls in vaccine acquisition and availability. Specifically, the DOD must collectively assess and prioritize all biological threats, whether natural, accidental, or deliberate in nature; consolidate redundant vaccine acquisition activities; elevate the priority of infectious-disease vaccines; and provide ample resources to sustain a robust vaccine acquisition capability to protect US military forces against validated and prioritized biological threats.[2]

This article first establishes the historical impact of naturally occurring infectious diseases on military operations, the criticality of force health protection (FHP) in defending the human weapon system, and the superiority of vaccines among medical countermeasures. It then makes a case for why US military leadership in R&D for infectious-disease vaccines must remain a vital FHP imperative for safeguarding the war fighter and optimizing the US military's mission effectiveness. Next, the article analyzes how unbalanced threat assessment and mission focus, disparate organization, disproportionate funding, and dissimilar priority status hinder the DOD's acquisition efforts regarding infectious-disease vaccines; in so doing, it points to the department's loss of adenovirus vaccine as an example of the program's decline. Finally, it recommends ways to enhance FHP vaccine acquisition and availability that will posture the DOD and America's military forces to assure national security in the twenty-first century.

## Historical Effect of Infectious Diseases on US Military Readiness and Effectiveness

Throughout America's wars, naturally acquired infectious diseases—many preventable by vaccine—have eclipsed bombs and bullets as the culprits of morbidity, mortality, disability, and mission degradation. As thousands of his troops fell ill—and hundreds died—from smallpox during the first two years of the American Revolution, resulting in campaign losses, poor morale, and sparse recruiting, Gen George Washington lamented, "Should the disorder infect the Army, in the natural way . . . we should have more to dread from it, than from the sword of the enemy."[3] Via inoculation, the Continental Army dramatically reduced smallpox mortality from 160 to 3.3 per 1,000 cases, all but eliminating the threat.[4] The US Civil War saw almost twice as many deaths from disease (65 per 1,000) as from battle (33 per 1,000).[5] Of the 6 million disease cases among 2.8 million enlistees on both sides, over 95,000 died and roughly 250,000 were discharged for disability.[6] Typhoid fever, malaria, and yellow fever accounted for 80 percent of US military deaths in the Spanish-American War, forcing a rapid withdrawal from Cuba soon after the end of hostilities.[7] Although World War I saw—for the first time—near parity between US deaths from battle (50,510) and disease (51,477), the latter's impact on combat operations was demoralizing.[8] Various diseases accounted for 95 percent of American battlefield hospital admissions in World War II, 69 percent in Vietnam, 71 percent in the first Gulf War, and over 95 percent in Somalia.[9] Unchecked, natural infections can wreak havoc on military forces.[10]

## Criticality of Force Health Protection in Defending the Human Weapon System

The DOD's FHP doctrine characterizes every service member as a human weapon system requiring total life-cycle support and health maintenance.[11] Protecting the human weapon system, the central element of military power, is pivotal. Absent "craniums at the controls," "boots on the ground," and "hands on deck," wars cannot be won. Strained budgets, emerging technologies,

and evolving threats have pressed the United States to transform its military into a lighter, leaner, and more agile force. With fewer people performing more specialized roles, it is critical that each military member remain healthy, fit, and effective. Maintaining this ideal can present a challenge since DOD personnel often find themselves in austere locations, on short notice, and under stressful conditions involving an abundance of naturally acquired infectious threats, naïve immune systems, and limited health-care support. A vital part of FHP, immunization is effective in mitigating these operational hurdles.[12]

## Superiority of Immunization among Medical Countermeasures

In defeating health threats, primary prevention—action prior to exposure—reigns supreme. Immunization affords the lowest risk, highest efficacy, and most cost-effective protection to vaccine recipients. Immunization is superior to therapeutics (e.g., antibiotics and chemoprophylactics) and personal protection (e.g., repellents and bed nets) since it does not require knowledge of exposure; is not contingent upon an accurate and timely diagnosis; protects against severe diseases (e.g., rabies) and those for which treatment is unavailable, ineffective, or prone to cause side effects; does not require individual compliance (e.g., antimalarials); and neither contributes to nor is fazed by microbial resistance. Immunization can also notably reduce the medical logistical footprint in-theater since every casualty requires five personnel in the evacuation and treatment support chain.[13] Furthermore, vaccines not only offer a direct benefit to recipients but also afford herd immunity to those in the communities with whom they live and work.[14] Finally, despite perceived differences between weaponized and natural pathogens, "vaccines are a unifying technology proven to effectively and efficiently defeat both of these threats."[15]

## The Case for US Military Leadership in Researching and Developing Infectious-Disease Vaccine

Fielding a licensed vaccine is a long, complex, high-risk endeavor. It requires the synergy of expertise and resources from multiple partners spanning government, industry, academia, nonprofits, and international organizations.[16] Managing the substantial scientific and financial risks demands cooperation. In general, no partner can develop and produce a vaccine countermeasure alone. The DOD, for instance, must rely on industry for scale-up production, just as industry relies on the DOD to bring its many unique R&D capabilities to the cooperative effort.[17] Nevertheless, the DOD should play a leading role in vaccine development for a number of reasons.

First, the DOD can draw on its unique experience. The US military codeveloped more than half of the routine vaccines given to service members today.[18] Beyond protecting its own forces, the military's advances also created solutions to diseases of dire importance to national and international public health. The DOD played a significant role in developing eight of the 15 adult vaccines licensed in the United States since 1962.[19] Currently used worldwide, these include vaccines for influenza, meningococcal disease, hepatitis A, hepatitis B, rubella, adenovirus, typhoid, and Japanese encephalitis.[20] In addition, investigators who began their careers at US military R&D centers supervised the development of licensed vaccines for yellow fever, mumps, measles, varicella, and oral polio.[21] In the high-risk business of vaccine production, experience breeds proficiency and efficiency, curbing the scientific, regulatory, and financial risk that can stifle product development.

Second, the DOD offers unique facilities. Currently, the Walter Reed Army Institute of Research houses one of the nation's three pilot facilities dedicated to the production of a variety of investigational vaccines for use in clinical trials.[22] Industry actively seeks

the institute's in-house laboratory capabilities to conduct animal modeling studies.

Third, the DOD features unique intellectual property sharing.[23] Highly sought after by industry, DOD partnerships attract companies by allowing them to retain intellectual property rights for use in lucrative civilian markets.[24]

Fourth, the DOD has a unique R&D network.[25] Because the Food and Drug Administration (FDA) requires pivotal clinical trials of products on people living in areas where infectious diseases are endemic, the DOD's overseas laboratories serve as bases for conducting trials that attract industry partnerships.[26] Because of its enduring presence, strong host-nation relationships, and professional development of host-nation scientists, the DOD has successfully executed complex clinical trials with industry and international partners.[27]

Fifth, and most important, the DOD focuses on the often unique needs of the war fighter. This mission distinguishes its infectious-disease activities from those of other organizations that conduct what may appear to be similar R&D. The global effort to develop antimalarial countermeasures provides one example. Outside the DOD, this effort emphasizes drug therapies to attenuate lethal disease in children and pregnant women in underdeveloped countries. The DOD's program, on the other hand, seeks to prevent the war fighter from ever contracting the debilitating illness in the first place. To that end, DOD research has concentrated on developing prophylactic drugs and, more recently, a malaria vaccine solution. Additionally, any drug or vaccine used to protect US war fighters must be licensed by the FDA. Because many companies are reluctant to take on this costly risk independently, the DOD's R&D community plays a key role in moving products with potential military relevance through early development, FDA licensure, and eventual use by the US military.[28]

Also compelling is the potential effect of infectious-disease vaccines on the military's increasing role in stability operations, which the DOD recently designated "a core US military mission that [it] should be prepared to conduct with proficiency equivalent to combat operations."[29] Infectious diseases contribute significantly to social unrest and conflict in these scenarios. Infections not only ravage the local civilian populace but also can decimate the strength of their national militaries. The prevalence of human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) in Africa serves as a persuasive example. Of 33 million people living with HIV worldwide, two-thirds reside in sub-Saharan Africa.[30] Armed forces in this region experience HIV infection rates two to three times those of the civilian population, further eroding local, national, and regional prospects for stability.[31] The following excerpt from a 2002 report by the Center for Strategic and International Studies well summarizes the significance of this US national security concern:

> In Africa, HIV/AIDS is spreading fastest in the Horn of Africa, where the United States already has deep concerns about lawlessness and extremism. In both Ethiopia and Kenya, potentially important regional hubs in the violent and volatile East African subregion, adult HIV-prevalence rates are over 10 percent. Nigeria, an essential guarantor of security and economic growth in the West African region, has more than 3 million citizens living with HIV or AIDS. The adult prevalence rate in South Africa, which plays a similar economic and security role in the southern African region, is 20 percent. . . . If these two regional hegemons cannot send peacekeepers, contribute to growth and stability, or guarantee their own internal stability, U.S. security interests in the continent . . . are severely threatened.[32]

This situation demonstrates the powerful potential effect that vaccines for endemic diseases could have on geopolitical stability.[33] An effective HIV vaccine could remarkably strengthen foreign militaries, secure vulnerable families and communities, bolster international public health, and reinforce US national security.[34]

Natural infections will continue to challenge the US military and its R&D community. With 1,500 known human pathogens continuously lurking about and novel agents like H1N1 (influenza A virus or "swine flu") constantly emerging, infectious diseases will remain a formidable national security threat indefinitely.[35] Worldwide, 14.7 million people die each year from known and preventable contagions.[36] Even in industrialized nations, 46 percent of all deaths result from infectious causes.[37] Discovery of emerging infections has occurred at the rate of one per year since the late 1980s.[38] Pathogens adapt, persist, and emerge—this pattern will continue.[39] Keeping pace with the evolving threat calls for a robust US military vaccine program for infectious diseases that draws on the venerable experience, proven track record, and unique attributes that no agency other than the DOD can bring to bear. Such a program can continually improve upon the department's unparalleled protection of America's warriors and, in the process, the nation's citizens and global neighbors.

## The Department of Defense's Unbalanced Biological-Threat Assessment and Mission Focus

Since the Cold War's end, the DOD has become fixated on combating biological threats of deliberate rather than natural origin. This section examines its lopsided focus on notional bioweapons even though natural infections continue to plague military operations.

### *Weaponized Pathogens: A Matter of National Insecurity*

Despite its remarkable history, the US military infectious-disease vaccine program has taken a backseat to countering the bioterrorism threat since the mid-1990s. Beginning with its stand-up of the Joint Program Office for Biological Defense in 1993 and formalized requirements for biodefense vaccines in 1995, the DOD—with a push from Congress—justifiably turned a focused eye to biodefense.[40] By 1998 the DOD had established the Joint Vaccine Acquisition Program (JVAP) and significantly increased funding for advanced biodefense vaccine development, while core funding for R&D involving infectious-disease vaccines declined.[41] Because of the anthrax letters (sent after the terrorist attacks of 11 September 2001), fears about the proliferation of state-sponsored weapons of mass destruction by Iraq, and al-Qaeda's interest in bioagents, the nation felt extremely vulnerable to biological attack.[42] The DOD responded with wholesale investments in biodefense as funding for infectious-disease R&D remained level.[43]

Reportedly, about a dozen states and multiple nonstate actors either possess or are pursuing biological weapons.[44] Their potential use clearly poses a level of danger to US forces in the contemporary battlespace, as do established and emerging natural infections. To date, the DOD has yet to incur a single case of weaponized disease, yet reports cite some 3,400 cases of natural-origin and vaccine-preventable infectious diseases in deployed US forces since 1998.[45] Certainly a potential threat, bioterrorism against US interests nevertheless has been limited to the sending of anthrax-tainted letters to 22 American citizens, five of whom died. Moreover, the letters may have come from a lone American researcher having no association with either state sponsors or nonstate actors.[46]

In contrast, by 2008 the West Nile virus had sickened 28,961 Americans—claiming 1,131 lives—since its arrival on US soil in 1999.[47] The emergence of severe acute respiratory syndrome in 2003, H5N1 (influenza A virus or "bird flu") in 2006, and H1N1 in 2009 further underscores the clear and present danger posed by natural infectious diseases. Also, to some experts, the emergence of a novel strain of adenovirus among military recruits in 2007 served to "remind us that we are at least equally likely . . . to soon experience large-scale

morbidity through epidemics of emergent pathogens" as we are to experience a biological weapons attack.[48] Undoubtedly, the United States must prepare its public and military for the intentional use of biological agents, but vigilance for natural infections warrants at least the same level of emphasis.

### *Natural Pathogens: An Operational Reality Check*

All the while, natural-origin infectious diseases continued to pose real challenges to US military commanders in terms of lost manpower days, reduced effectiveness, increased medical visits, and frequent medical evacuations.[49] In one triservice study, of 15,459 Operation Iraqi Freedom and Operation Enduring Freedom deployers surveyed, up to 75 percent reported having at least one bout of diarrhea, 69 percent suffered one or more episodes of acute respiratory illness, and "one-quarter believed that combat unit effectiveness had been negatively affected by these common illnesses."[50] Twenty-five percent of those surveyed required intravenous fluids, and over 10 percent were hospitalized during their deployments. Furthermore, roughly 13 percent of ground-force personnel missed at least one patrol, and 12 percent of aircrew members were grounded.[51]

Table 1 summarizes the incidence of the four leading—and potentially vaccine-preventable—infectious diseases in deployed US forces between 1998 and 2009. Of the 3,371 total cases, leishmaniasis, malaria, and Lyme disease accounted for 96.3 percent of the disease burden. Through 2004, leishmaniasis prompted 4.4 percent of the monthly medical evacuations during Iraqi Freedom.[52] The occurrence of 126 cases of meningococcal disease reflects the absence of an effective vaccine for subtype B of this potentially lethal pathogen. Each of these operational experiences emphasizes the current threat from naturally acquired pathogens and justifies continued development of vaccine solutions for the mission-crippling diseases they cause.

**Table 1. Summary of the major, potentially vaccine-preventable infectious diseases incurred by deployed US military forces, 1998–2009**

| | *Leishmaniasis* | *Malaria* | *Lyme Disease* | *Meningococcal Disease* |
|---|---|---|---|---|
| Active | 771 | 990 | 551 | 106 |
| Reserve | 420 | 68 | 445 | 20 |
| Total | 1,191 | 1,058 | 996 | 126 |

*Data from* "Defense Medical Surveillance System," Armed Forces Health Surveillance Center, 10 December 2009.

## Signs of a Program in Serious Decline: Loss of Adenovirus Vaccine

While the DOD shifted its emphasis to biodefense, the department lost ground in its portfolio of infectious-disease vaccines. Major vaccine shortfalls resulted from a variety of economic, regulatory, scientific, and legal pressures that the existing DOD vaccine-acquisition apparatus could not mitigate (table 2). Previously licensed vaccines for Lyme disease, cholera, and plague are currently unavailable. Ten investigational new drug (IND) vaccines are no longer produced and have limited availability.

The most instructive example is the DOD's loss of adenovirus vaccine. Because of crowding and various stressors, adenovirus frequently causes acute respiratory disease in unvaccinated military recruits.[53] Prior to the initiation of routine immunization in 1971, adenoviral outbreaks in DOD basic-training units were common. Infection rates approached 50 percent, hospitalizations reached 10 percent, and occasionally trainees died.[54] Outbreaks stressed medical services, eroded training effectiveness, and sometimes stalled the training pipeline altogether.[55] During 25 years of use, the adenovirus vaccine provided to recruits on day one of training virtually eliminated the disease.[56] In the mid-1990s, however, negotiations between the DOD and the sole manufacturer of adenovirus vaccine failed to produce a financial agreement

**Table 2. Shortfalls of previously licensed and IND-only infectious-disease vaccines**

| | *Vaccine* |
|---|---|
| Previously licensed but unavailable | Adenovirus, types 4 and 7 |
| | Lyme disease |
| | Cholera |
| | Plague |
| IND product no longer produced and of limited availability | Argentine hemorrhagic fever |
| | Chikungunya virus |
| | Eastern equine encephalitis |
| | Q fever |
| | Rift Valley fever |
| | Tularemia |
| | Venezuelan equine encephalitis |
| | Western equine encephalitis |
| | Botulinum toxoid |
| | Tickborne encephalitis |

*Data from* Stanley M. Lemon et al., eds., *Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military* (Washington, DC: Institute of Medicine of the National Academies, National Academies Press, 2002), 44–45.

concerning upgrades to the production facility required by the FDA. In 1996 the manufacturer could no longer afford to produce the vaccine. As supplies waned across the DOD, prevaccination program morbidity returned, with unvaccinated trainees 28 times more likely than vaccinated trainees to test positive for the types of adenovirus covered by the vaccine.[57] All stocks were depleted by 1999, and by the end of 2000, seven basic military training centers had experienced adenoviral epidemics.[58]

Today, the DOD still has no adenovirus vaccine, and the disease continues to sicken trainees, burden medical systems, and disrupt training.[59] For the 12 months prior to December 2009, over 4,400 military recruits with febrile respiratory illness tested positive for adenovirus.[60] Not all who became ill were tested; the actual number of cases was higher.[61] One DOD study found the loss of adenovirus vaccine responsible for an estimated 10,650 preventable infections, 4,260 visits to medical clinics, and 852 hospitalizations among the roughly 213,000 active duty and reserve trainees enrolled in basic training each year.[62] Another study projected $26.4 million as the related annual medical and training costs for the US Army alone.[63]

The loss of adenovirus vaccine "sounds a warning for the fragile system supporting other vaccines of military and public health importance."[64] To stay in business, vaccine manufacturers need to realize a profit. To do so, they must weigh what it costs to manufacture a product, how much of it they can sell at what price, and what they could make if they used their production capacity on a different product. The economic pressures brought on by evolving regulatory requirements caused this sole-source manufacturer to abandon its production of a limited-market vaccine used mainly by the military. Competing priorities and the lack of a single agent with the authority and budget to preserve the availability of adenovirus vaccine were significant DOD shortcomings.

## Disparate Organizations, Disproportionate Funding, and Dissimilar Priority

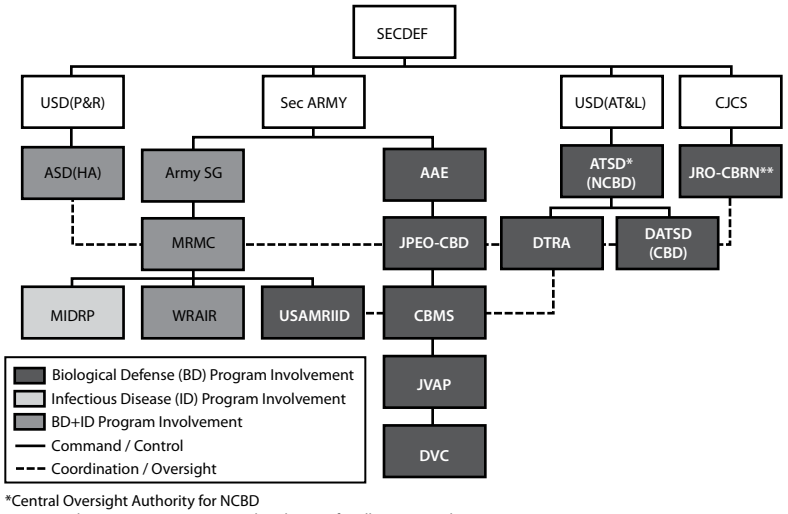
Despite overlapping missions, the DOD maintains separate organizations for the development, procurement, and product management of infectious-disease and biodefense vaccines. Each has exclusive budgetary authority and product-line responsibility. This section investigates the negative consequences of the DOD's decision to decouple its vaccine programs while granting preferential funding and priority to its biodefense efforts.

### *Disparate Organizations*

"The mission of the Military Infectious Diseases Research Program (MIDRP) is to protect the U.S. military against naturally occurring infectious diseases via the development of [FDA-]approved vaccines" and other protection systems.[65] The JVAP exists to "develop,

produce and stockpile FDA-licensed vaccine systems to protect the warfighter from biological agents."[66] These agencies feature disparate command and control relationships (fig. 1). In reality, the number of players and interactions is much more complex, indicative of the fragmented and diffuse organization that encumbers acquisition. Congress directed the split-management scheme to raise the visibility of biodefense and streamline acquisition procedures.[67] In retrospect, however, separating the acquisition of infectious-disease and biodefense vaccines was ill advised for multiple reasons.

First, separate acquisition precludes a unified approach to the identification and prioritization of vaccine solutions based primarily on operational risk rather than the nature of the threat. Similarly, it impedes a united approach to the acquisition of "dual-use" vaccines, those that could counter both a natural and a weaponized threat to military personnel.[68] The National Select Agent Registry, utilized for monitoring the possession and use of 48 pathogens and toxins that pose a severe threat to human health, contains 13 bioweapons that are also natural infections for which vaccines have been,




| | |
|---|---|
| **AAE** | Army Acquisition Executive |
| **Army SG** | Army Surgeon General |
| **ASD(HA)** | Assistant Secretary of Defense for Health Affairs |
| **ATSD(NCBD)** | Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs |
| **CBMS** | Chemical-Biological Medical Systems |
| **CJCS** | Chairman of the Joint Chiefs of Staff |
| **DATSD(CBD)** | Deputy Assistant Secretary of Defense for Chemical and Biological Defense Programs |
| **DTRA** | Defense Threat Reduction Agency |
| **DVC** | DynCorp Vaccine Company (Prime Systems Contractor) |
| **JPEO-CBD** | Joint Program Executive Office-Chemical and Biological Defense |
| **JRO-CBRN** | Joint Requirements Office-Chemical, Biological, Radiological, Nuclear |
| **JVAP** | Joint Vaccine Acquisition Program |
| **MIDRP** | (US Army) Military Infectious Diseases Research Program |
| **MRMC** | (US Army) Medical Research and Materiel Command |
| **Sec Army** | Secretary of the Army |
| **SECDEF** | Secretary of Defense |
| **USAMRIID** | US Army Medical Research Institute of Infectious Diseases |
| **USD(AT&L)** | Under Secretary of Defense for Acquisition, Technology, and Logistics |
| **USD(P&R)** | Under Secretary of Defense for Personnel and Readiness |
| **WRAIR** | Walter Reed Army Institute of Research |

**Figure 1. Simplified organizational chart depicting DOD infectious-disease and biodefense vaccine programs**. (Adapted from Lt Col Coleen K. Martinez, "Biodefense Research Supporting the DOD: A New Strategic Vision," Research Report no. 1-58487-288-8 [Carlisle Barracks, PA: US Army War College, 2007], 11; Rudolph Kuppers, US Army Medical Research and Materiel Command [USMRMC] / Military Infectious Diseases Research Program [MIDRP], to the author, e-mail, 11 December 2009; and Col Charles Hoke, MD, US Army Medical Research Institute for Infectious Diseases, retired, to the author, e-mail, 24 January 2010.)

or currently are, in some stage of development by the MIDRP.[69]

Second, separate acquisition fosters programmatic redundancy. Many more similarities than differences exist among the pathogens, science, technology, and business processes for vaccines against natural and weaponized agents. Their development and production follow like pathways, encounter similar difficulties, and present comparable developmental and financial risks.

Third, separate acquisition dilutes limited expertise and splits budgetary power. The complexity of vaccine development demands highly skilled and experienced professionals in all facets, from scientists to administrators. Also, the industry average cost to bring a new vaccine through the development process from concept to licensure ranges from $800 million to $1.6 billion over 14 years; to sustain a fielded product costs millions more. Separation curbs professional and budgetary synergy.[70]

Fourth, separate acquisition hinders the Total Life-Cycle Systems Management (TLCSM) of vaccine products—"the implementation, management, and oversight, by [a single accountable authority], of all activities associated with the acquisition, development, production, fielding [and] sustainment . . . of a DOD weapon system across its life cycle."[71] The Joint Program Executive Office for Chemical and Biological Defense leads the TLCSM of biodefense vaccines.[72] To date, no single locus of TLCSM authority, responsibility, and accountability exists for infectious-disease vaccine products.[73] Separation underserves the acquisition of infectious-disease vaccine and precludes collaboration in enterprisewide vaccine TLCSM.

These issues have contributed to significant problems in vaccine availability, such as the loss of the adenovirus vaccine, as previously described. They also signify the level of commitment required by the DOD not only to bring militarily important vaccines on line but also to keep them available.[74] In its 2002 report to the DOD, the Institute of Medicine was "convinced that the disjointed authority . . . within DOD contributed significantly to the lack of the additional investment required for continued production of [adenovirus] vaccine."[75]

### *Disproportionate Funding*

Although discrete programs with no single oversight authority are problematic, the pivotal issue in separating the acquisition of infectious-disease and biodefense vaccines is budgetary. In 1993 the DOD's annual budget for the advanced development of biodefense vaccines amounted to $1 million.[76] By 1998 funding levels had risen to $25 million per year.[77] Between fiscal year (FY) 2001 and FY 2008, the US government allocated $57 billion to biodefense, the DOD receiving nearly $12 billion.[78] In FY 2009, governmentwide allocations jumped by 39 percent over the previous year to $8.97 billion; the DOD share came to $1.72 billion.[79] The Department of Health and Human Services and the DOD received billions to develop, produce, procure, and stockpile vaccine countermeasures against weaponized pathogens.[80] Since FY 1997, the annual US budget for biological defense has increased over 47-fold, from $137 million to $6.5 billion by FY 2008.[81]

Several points arise regarding MIDRP funding for its core research since 1994 and projections to FY 2011 (fig. 2). First, management of biodefense vaccine transitioned from the MIDRP to the JVAP in 1998, accounting for the associated funding spike and subsequent dip. Second, there is a relative budget flatline in actual-year dollars over the period. In FY 1994, the MIDRP's annual budget was $42 million. By FY 2009, it had increased only to $47 million. Third, when adjusted for inflation to FY 2005 dollars, the buying power of the FY 2009 budget came to only $41 million, less than that of 15 years earlier. Fourth, the inflationary gap is widening. In FY 2011, the MIDRP's $46 million annual budget is worth, in effect, roughly $37 million in FY 2005 dollars.

Inflation has a mounting effect on the MIDRP budget through FY 2015 (fig. 3). Given the projected funding levels, the MIDRP cannot keep pace with inflation. This

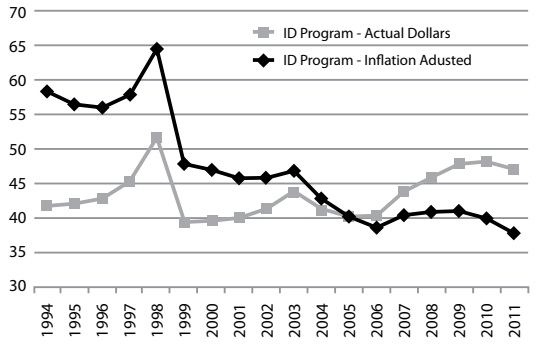



**Figure 2. US Army MIDRP funding for core research on infectious diseases (with inflation adjusted to FY 2005, in millions of dollars, exclusive of the HIV program)**. (Adapted from Rudolph Kuppers, USMRMC/MIDRP, to the author, e-mail, 11 December 2009.)

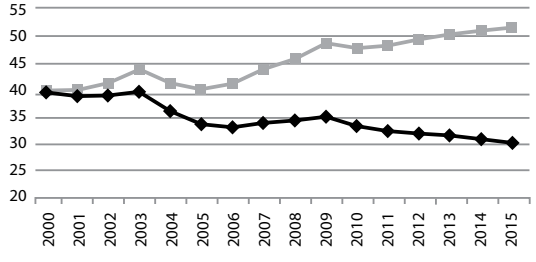



**Figure 3. US Army MIDRP budget (FY 2000–15, in millions of dollars, exclusive of the HIV program)**. (Adapted from Rudolph Kuppers, USMRMC/MIDRP, to the author, e-mail, 11 December 2009.)

dismal scenario is exacerbated by the rising cost of advanced product development and clinical trials, which accounts for roughly 75 percent of total development outlays.[82] Also, clinical trials on human subjects to assess a vaccine's safety and efficacy are very expensive. In the past five years, these costs have risen from $15,000 to as much as $26,000 per enrollee.[83] In light of static funding and less buying power, the MIDRP's ability to develop vaccine products is, and will remain, seriously constrained.

### *Dissimilar Priority*

To make the best use of limited resources, the Defense Acquisition Management System has rules that govern the acquisition of military vaccines. Acquisition categories (ACAT I, II, and III) assign priority and determine the level of DOD review, decision authority, and milestones that apply to a given project.[84] On the one hand, the MIDRP's infectious-disease vaccines are now managed as an ACAT III "less than major" program, the lowest priority level, with each vaccine managed as a separate acquisition project.[85] On the other hand, the JVAP develops biodefense vaccines as an ACAT II "major system" program under the Joint Program Executive Office for Chemical and Biological Defense.[86] The ACAT II designation affords biodefense vaccines not only higher priority for acquisition funding but also higher visibility than vaccines against infections of natural origin. The lack of emphasis on these natural infectious-disease countermeasures has contributed to the loss of licensed vaccines (e.g., adenovirus, plague, and cholera) and the inability to advance IND products (e.g., tickborne encephalitis, Rift Valley fever, and eastern equine encephalitis vaccines) to full licensure. Additionally, the inferior priority of infectious-disease vaccines makes their funding vulnerable to becoming offsets for higher ACAT programs.

## Recommendations

This section recommends four imperatives for ensuring the DOD's ongoing ability to produce vaccines against natural infections and offers final thoughts on reversing the dangerous decline in the US military's ability

to conduct infectious-disease R&D. The challenges are formidable, but the DOD can cure its ailing infectious-disease vaccine program and regain its former status as the world's premier force health defender.

***Redesign the Biological-Threat Assessment Process***

The DOD should concurrently consider all biothreats, regardless of origin, and then prioritize them based on a balanced assessment of notional and experiential risks to war fighters, independent of the nature of the threat.[87] To facilitate this process, it should institute a standardized cost-benefit computation for candidate vaccines and strategies, where solutions to natural or weaponized biothreats with the most compelling calculations garner the highest priority for funding.[88]

***Merge the Management of Infectious-Disease and Biodefense Vaccines***

The DOD should have a single program to unify needs identification, prioritization, basic and advanced research, production, procurement, and ongoing product management.[89] We must vest program leadership in a single agent with the authority, responsibility, and accountability for ensuring effective TLCSM of all vaccines that protect war fighters against natural and weaponized pathogens. Combining programs will facilitate the synergistic sharing of ideas, expertise, and resources; incentivize cohesive thinking on vaccine solutions of mutual benefit to infectious-disease prevention, biodefense, and public health; and underpin the maintenance of a robust, adaptable technology base that can flex to conduct timely research on the moving target of natural and weaponized biothreats. In addition, a unified program champion will provide the strongest advocacy for infectious-disease vaccines to balance against the government's proclivity for biodefense countermeasures.

***Elevate the Acquisition Priority of Infectious-Disease Vaccines***

Like those intended for biodefense, vaccines to counter natural infections deserve management at the ACAT II major-system level (or higher). Doing so would be consistent with the first recommendation, above, to consider all biological threats—regardless of origin—of equal potential harm to war fighters. This priority will ensure appropriate visibility of and emphasis on the acquisition of both infectious-disease and biodefense vaccines within the DOD.

***Increase Funding for Research, Development, and Procurement of Infectious-Disease Vaccines***

In addition to raising overall program funding, the DOD should fund each infectious-disease vaccine as a separate line item in the Future Years Defense Program to ensure TLCSM.[90] These are the most important actions the department must take. To be clear, we do not need a zero-sum realignment of resources for biodefense and infectious-disease vaccines. Biodefense vaccines should remain fully funded, with relative parity achieved for the development of infectious-disease vaccine. Currently, at least half of national biodefense funding serves both biodefense and public health ends.[91] This kind of overlap should become the rallying cry of DOD vaccine prioritization and resource allocation. A successful biothreat vaccine program demands cooperation, not competition.

## Conclusion

The president's 2009 *National Strategy for Countering Biological Threats* calls for "a comprehensive and integrated approach . . . to prevent the full spectrum of biological threats . . . whether . . . natural, accidental, or deliberate [in nature]."[92] To meet his intent, the DOD needs to reorganize its current infectious-disease and biodefense vaccine-acquisition stovepipes and establish a

unified program to effectively assess, prioritize, develop, and procure vaccines to protect war fighters against threats from all causes.

Staying ahead of the changing threat requires the DOD to refocus on the full range of biothreats and commit ample resources to the sustained development of vaccines for infectious diseases as well as biodefense. Anything less places force health, combat readiness, and operational effectiveness at serious risk. ✪

## Notes

1. In this article, *acquisition* denotes the DOD's process for ensuring that vaccines are acquired and maintained for the protection of its forces, from needs identification, prioritization, and basic research to advanced development, testing, production, and procurement. *Availability* involves having on hand the right vaccine for the right threat at the right time.

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3. Stanhope Bayne-Jones, *The Evolution of Preventive Medicine in the United States Army, 1607–1939* (Washington, DC: Office of the Surgeon General, Department of the Army, 1968), 52, accessed 28 October 2009, http://history.amedd.army.mil/booksdocs/misc/evprev/default.html.

4. Specifically, this was *variolation*, an "obsolete process of inoculating a susceptible person with material taken from a vesicle of a person who has smallpox." *WordNet*, Princeton University, http://wordnetweb.princeton.edu/perl/webwn?s=variolation.

5. Bayne-Jones, *Evolution of Preventive Medicine*, 99.

6. Ibid.

7. Ibid., 124.

8. Ibid., 151.

9. Mark S. Riddle et al., "Past Trends and Current Status of Self-Reported Incidence and Impact of Disease and Nonbattle Injury in Military Operations in Southwest Asia and the Middle East," *American Journal of Public Health* 98, no. 12 (2008): 2199; and Stanley M. Lemon et al., *Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military* (Washington, DC: Institute of Medicine of the National Academies, National Academies Press, 2002), 10.

10. John W. Sanders et al., "Impact of Illness and Non-Combat Injury during Operations Iraqi Freedom and Enduring Freedom (Afghanistan)," *American Journal of Tropical Medicine and Hygiene* 73, no. 4 (2005): 713–19, accessed 21 October 2010, http://www.ajtmh.org/cgi/reprint/73/4/713.

11. Joint Publication (JP) 4-02, *Health Service Support*, 31 October 2006, GL-14, accessed 21 October 2010, http://www.dtic.mil/doctrine/new_pubs/jp4_02.pdf; Lt Col Anthony P. Tvaryanas, Col Lex Brown, and Nita L. Miller, PhD, "Managing the Human Weapon System: A Vision for an Air Force Human-Performance Doctrine," *Air and Space Power Journal* 23, no. 2 (Summer 2009): 34–41; and Joint Chiefs of Staff (JCS), *Force Health Protection Capstone Document* (Washington, DC: JCS, 2000), 2, http://www.deploymentlink.osd.mil/pdfs/fhp2004.pdf.

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13. Richard D. Nidel, JVAP Office video, accessed 5 December 2009, http://www.jpeocbd.osd.mil/packs/DocHandler.ashx?DocId=4711.

14. John D. Grabenstein, "Immunization to Protect the US Armed Forces: Heritage, Current Practice, and Prospects," *Epidemiologic Reviews* 28, no. 1 (2006): 10, accessed 21 October 2010, http://epirev.oxfordjournals.org/content/28/1/3.full.pdf+html.

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16. Rudolph Kuppers, US Army Medical Research and Materiel Command (USMRMC)/Military Infectious Diseases Research Program (MIDRP), to the author, e-mail, 11 December 2009.

17. Ibid.

18. Ibid.

19. "History and Achievements," MIDRP, accessed 5 January 2010, https://midrp.amedd.army.mil/info/HAchieve.html.

20. Ibid.

21. Ibid.

22. "CBRN Medical Countermeasures (MCM) Manufacturing Capabilities Analysis of Alternatives Report" (Livingston, NJ: The Quantic Group, 15 June 2009), 10.

23. Intellectual property is "the group of legal rights to things people create or invent. Intellectual property rights typically include patent, copyright, trademark and trade secret rights." "Glossary," *Sitepoint*, accessed 21 October 2010, http://www.sitepoint.com/glossary.php?q=I.

24. Kuppers to the author, e-mail; and Lemon et al., *Protecting Our Forces*, 87.

25. Col Charles Hoke, retired, MD, US Army Medical Research Institute for Infectious Diseases, to the author, e-mail, 24 January 2010.

26. A pivotal clinical trial must be controlled, have a double-blinded design when practical and ethical, be randomized, and be of adequate size. See "Appendices—Clinical Trials Insight," *AdisInsight*, 2000, accessed 21 October 2010, http://www.adisinsight.com/aClientServiceinfo/CTI%20Appendix.pdf. DOD overseas labs are located in Thailand, Peru, Kenya, Egypt, and Indonesia. Hoke to the author, e-mail.

27. Col Julia Lynch, USMRMC/MIDRP, to the author, e-mail, 18 January 2010.

28. Kuppers, to the author, e-mail.

29. Department of Defense Instruction (DODI) 3000.05, *Stability Operations*, 16 September 2009, 2, accessed 21 October 2010, http://www.dtic.mil/whs/directives/corres/pdf/300005p.pdf.

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31. Mark Schneider and Michael Moodie, *The Destabilizing Impacts of HIV/AIDS* (Washington, DC: Center for Strategic and International Studies, May 2002), 2, accessed 21 October 2010, http://www.reliefweb.int/rw/lib.nsf/db900SID/LGEL-5DWGVF/$FILE/csis-aids-may02.pdf?OpenElement.

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33. Kuppers to the author, e-mail.

34. In June 2009, a US Army–led phase-three community-based trial of a candidate HIV vaccine was completed, yielding encouraging preliminary results but requiring further research. Hoke to the author, e-mail.

35. Lynch to the author, e-mail; and W. Neal Burnette et al., "Infectious Diseases Investment Decision Evaluation Algorithm: A Quantitative Algorithm for Prioritization of Naturally Occurring Infectious Disease Threats to the U.S. Military," *Military Medicine* 173, no. 2 (February 2008): 174–81.

36. Sara E. Davies, "Securitizing Infectious Disease," *International Affairs* 84, no. 2 (2008): 295–313; and WHO, "The Top Ten Causes of Death," fact sheet, February 2007, accessed 15 January 2010, http://www.who.int/mediacentre/factsheets/fs310.pdf. The top five infectious-disease killers include HIV/AIDS, pneumonia, diarrhea, malaria, and tuberculosis; arguably, climate change is significantly changing weather patterns and disrupting ecosystems, leading to the emergence of new niches for infectious-disease pathogens and vectors. Lynch to the author, e-mail.

37. Burnette et al., "Infectious Diseases Investment," 174.

38. Davies, "Securitizing Infectious Disease," 298.

39. Hoke to the author, e-mail.

40. Edward T. Clayson, Joint Vaccine Acquisition Program (JVAP) Product Management Office, JVAP overview presentation slides, 30 May 2003, slide 5.

41. Ibid.; and Kuppers to the author, e-mail (compares 1997 and 1999 MIDRP funding).

42. US Senate, *Testimony for the Senate Foreign Relations Committee by Amy Sands, PhD, Deputy Director, Center for Non-Proliferation Studies, Monterey Institute of International Studies, before the US Senate Foreign Relations Committee*, 107th Cong., 2d sess., 19 March 2002, accessed 7 January 2010, http://cns.miis.edu/pubs/reports/asands.htm; and Lt Col Coleen K. Martinez, "Biodefense Research Supporting the DOD: A New Strategic Vision," Research Report no. 1-58487-288-8 (Carlisle Barracks, PA: US Army War College, 2007), 23.

43. Kuppers to the author, e-mail.

44. US Senate, *Statement by Assistant Secretary of State for Intelligence and Research Carl W. Ford, Jr. before the US Senate Committee on Foreign Relations Hearing on Reducing the Threat of Chemical and Biological Weapons*, 107th Cong., 2d sess., 19 March 2002, accessed 7 January 2010, http://www.fas.org/bwc/news/testimony/CT2002March19Ford.htm; and US Senate, *Testimony by Amy Sands*.

45. "Defense Medical Surveillance System," Armed Forces Health Surveillance Center, accessed 10 December 2009, http://www.afhsc.mil/dmss.

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"Adenovirus 14: An Emerging Threat," 17 April 2009, Clinicians' Biosecurity Network, accessed 27 November 2009, http://www.upmc-cbn.org/report_archive/2009/ 04_April_2009/cbnreport_04172009.html.

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50. Ibid., 714. *Campylobacter*, *Shigella*, *Escherichia coli* and norovirus have been the most commonly reported diarrheal infections in deployed forces. *Rhinovirus*, *Coronovirus*, parainfluenza virus, and adenovirus have been the most commonly reported causes of acute respiratory infections in deployed forces. "Defense Medical Surveillance System."

51. Sanders et al., "Impact of Illness and Non-Combat Injury," 716.

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53. James Chin, ed., *Control of Communicable Diseases Manual*, 17th ed. (Washington, DC: American Public Health Association, 2000), 428.

54. Grabenstein, "Immunization to Protect the US Armed Forces," 13.

55. Gregory C. Gray et al., "Adult Adenovirus Infections: Loss of Orphaned Vaccines Precipitates Military Respiratory Disease Epidemics," *Clinical Infectious Diseases* 31, no. 3 (September 2000): 663–70, accessed 21 October 2010, http://www.journals.uchicago.edu/doi/pdf/10.1086/313999.

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58. Gray et al., "Adult Adenovirus Infections," 668.

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Ahead Project Workshop, 16 September 2009), 2; and Center for Arms Control and Non-Proliferation, *Federal Funding for Biological Weapons Prevention*.

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